Docket No.: 514572000500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Dong LIANG et al. Application No.: 10/537,533 Filed: (Int'l) December 31, 2002 For: MICROMINIATURE GAS CHROMATOGRAPH COLUMN	Confirmation No.: 4778 Art Unit: 1797 Examiner: Dirk Bass

REQUEST FOR CONTINUED EXAMINATION AND PRELIMINARY AMENDMENT

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

INTRODUCTORY COMMENTS

This Preliminary Amendment accompanies a Request for Continued Examination (RCE) for the above-referenced application. A final Office Action was mailed on April 14, 2009 ("the OA"), for which a response is due on July 14, 2009. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 10 of this paper.

AMENDMENTS TO THE CLAIMS

1. (currently amended): A gas chromatograph column, which column comprises ~~at least~~ more than two discrete lid layers and [[a]] more than one discrete channel layer,

wherein each of said lid and channel layers comprises a compact material suitable for a gas chromatograph,

said channel ~~layer comprises~~ layers comprise microfabricated channels on both sides,

said microfabricated channels and sides of said lid layers form at least ~~two~~ four capillaries,

said at least ~~two~~ four capillaries are connected to each other through ~~a hole~~ holes in said channel ~~layer~~ layers and said lid layers to form an integrated capillary,

said integrated capillary is connected to outside atmosphere on both ends via holes on two outermost lid layers to serve as an inlet and an outlet[[,]]

~~said lid and channel layers have a thickness ranging from about 0.1 to 5 mm~~.

2. (canceled)

3. (currently amended): The gas chromatograph column of claim 1, which comprises three discrete lid layers and two discrete channel layers and [[an]] said integrated capillary is formed through all the lid and channel layers.

4. (previously presented): The gas chromatograph column of claim 1, wherein the compact material is metal.

5. (previously presented): The gas chromatograph column of claim 1, wherein the lid layers and the channel layer comprise the same compact material.

6. (original): The gas chromatograph column of claim 1, wherein the lid layers have an area ranging from about 1 to about 100 cm^2.

7. (original): The gas chromatograph column of claim 1, wherein the channel layer has an area ranging from about 1 to about 100 cm^2.

8. (previously presented): The gas chromatograph column of claim 1, wherein the lid layers and the channel layer have the same area.

9. (canceled)

10. (original): The gas chromatograph column of claim 1, wherein the microfabricated channels have a width ranging from about 1 to about 1,000 microns.

11. (original): The gas chromatograph column of claim 1, wherein the microfabricated channels have a depth ranging from about 3 to about 500 microns.

12. (original): The gas chromatograph column of claim 1, wherein the microfabricated channels are formed by a wet etching method.

13. (original): The gas chromatograph column of claim 1, wherein the microfabricated channels are formed by a dry etching method.

14. (original): The gas chromatograph column of claim 1, wherein the integrated capillary has a total length of at least 4 meters.

15. (previously presented): The gas chromatograph column of claim 1, wherein the integrated capillary has a sectional shape selected from the group consisting of a trapezoid, a rectangle, a circle, a semicircle, a sector and a combination thereof.

16. (original): The gas chromatograph column of claim 1, wherein the cross-section of the integrated capillary has an area ranging from about 5 to about 250,000 square microns.

17. (original): The gas chromatograph column of claim 1, wherein the integrated capillary has identical or different cross-section area(s) along its length.

18. (original): The gas chromatograph column of claim 1, wherein the integrated capillary has a serpentine or spiral pattern.

19. (original): The gas chromatograph column of claim 1, wherein the wall of the integrated capillary is coated with a thin film of a stationary phase.

20. (original): The gas chromatograph column of claim 19, wherein the stationary phase is applied via a deposition method, a dynamic lining method or a static lining method.

21. (original): The gas chromatograph column of claim 19, wherein the stationary phase is applied before or after the layers are bound together.

22. (original): The gas chromatograph column of claim 1, wherein the hole in the channel layer and the holes in the lid layers have a square or a round shape.

23. (original): The gas chromatograph column of claim 1, wherein the hole in the channel layer and the holes in the lid layers are formed by laser ablation, micromachining or etching.

24. (original): The gas chromatograph column of claim 1, wherein the layers are bound together by anodic bonding, ultrasonic welding, heat bonding or gluing.

25. (original): The gas chromatograph column of claim 1, which further comprises a heater wire deposited on an outside surface of the integrated capillary to provide for electric heating of a stationary phase material within the integrated capillary during operation of a gas chromatograph.

26. (canceled)

27. (currently amended): ~~The gas chromatograph column of claim 26~~ A gas chromatograph column, which column comprises at least two discrete lid layers and at least two discrete channel layers,

wherein each of said lid and channel layers comprises a compact material suitable for a gas chromatograph,

each of said channel layers comprises a microfabricated channel on at least one side,

said microfabricated channels and sides of said lid or channel layers form at least two capillaries,

said at least two capillaries are connected to each other through a hole in a channel and lid layer to form an integrated capillary, and

said integrated capillary is connected to outside atmosphere on both ends via holes on two outermost lid layers to serve as an inlet and an outlet,

wherein at least one of the channel layers comprises a microfabricated channel on one side, and the other side of the same channel layer directly faces a microfabricated channel of another channel layer to form a capillary.

28. (currently amended): ~~The gas chromatograph column of claim 26~~ A gas chromatograph column, which column comprises at least two discrete lid layers and at least two discrete channel layers,

wherein each of said lid and channel layers comprises a compact material suitable for a gas chromatograph,

each of said channel layers comprises a microfabricated channel on at least one side,

said microfabricated channels and sides of said lid or channel layers form at least two capillaries,

said at least two capillaries are connected to each other through a hole in a channel and lid layer to form an integrated capillary, and

said integrated capillary is connected to outside atmosphere on both ends via holes on two outermost lid layers to serve as an inlet and an outlet,

wherein at least one of the channel layers comprises microfabricated channels on both sides, and said microfabricated channels and sides of the lid layers form at least two capillaries.

29. (withdrawn): A gas chromatograph system, which system comprises:

(a) a gas injector for introducing a mobile phase including a sample gas in a carrier gas;

(b) a gas chromatograph column of claim 1 comprising a stationary phase suitable for gas chromatograph and mechanically connected to receive said mobile phase from said gas injector for the separation of an analyte in said sample gas; and

(c) a detector mechanically connected to said column for the analysis of said separated analyte of said sample gas with an electronic means.

30. (withdrawn): A gas chromatograph system, which system comprises:

(a) a gas injector for introducing a mobile phase including a sample gas in a carrier gas;

(b) a gas chromatograph column of claim 26 comprising a stationary phase suitable for gas chromatograph and mechanically connected to receive said mobile phase from said gas injector for the separation of an analyte in said sample gas; and

(c) a detector mechanically connected to said column for the analysis of said separated analyte of said sample gas with an electronic means.

31. (withdrawn): A method for analyzing an analyte in a sample, which method comprises:

(a) providing a gas chromatograph system of claim 29;

(b) vaporizing a sample to a gas phase;

(c) injecting said sample gas in a carrier gas into said gas chromatograph system; and

(d) allowing separation and detection of an analyte in said sample in said gas chromatograph system to assess the presence, absence or amount of said analyte in said sample.

32. (withdrawn): The method of claim 31, wherein the analyte is a molecule or an aggregate or complex thereof.

33. (withdrawn): The method of claim 32, wherein the molecule is selected from the group consisting of an inorganic molecule, an organic molecule and a complex thereof.

34. (withdrawn): The method of claim 33, wherein the organic molecule is selected from the group consisting of methane, chloroform, benzene and butyric acid.

35. (withdrawn): The method of claim 31, wherein the analyte is selected from the group consisting of a chemical compound, a metabolite of a chemical compound and a complex thereof.

36. (withdrawn): The method of claim 31, wherein the sample is mammalian sample.

37. (withdrawn): The method of claim 36, wherein the mammal is selected from the group consisting of bovine, goat, sheep, equine, rabbit, guinea pig, murine, human, feline, monkey, dog and porcine.

38. (withdrawn): The method of claim 31, wherein the sample is a clinical sample.

39. (withdrawn): The method of claim 38, wherein the clinical sample is selected from the group consisting of serum, plasma, whole blood, sputum, cerebral spinal fluid, amniotic fluid, urine, gastrointestinal contents, hair, saliva, sweat, gum scrapings and tissue from biopsies.

40. (withdrawn): The method of claim 38, wherein the clinical sample is a human clinical sample.

41. (withdrawn): The method of claim 31, wherein the sample is a body fluid sample.

42. (withdrawn): The method of claim 31, wherein the sample is an atmosphere, water, soil, drug or explosive sample.

43. (withdrawn): The method of claim 31, wherein the carrier gas is an inert gas.

44. (withdrawn): The method of claim 43, wherein the inert gas is selected from the group consisting of nitrogen, hydrogen, helium and argon.

45. (withdrawn): The method of claim 31, wherein the sample is vaporized in a carrier gas.

46. (withdrawn): The method of claim 31, wherein the sample is vaporized in the absence of a carrier gas and is then mixed before or while injected into the gas chromatograph system.

47. (withdrawn): A method for analyzing an analyte in a sample, which method comprises:

(a) providing a gas chromatograph system of claim 30;

(b) vaporizing a sample to a gas phase;

(c) injecting said sample gas in a carrier gas into said gas chromatograph system; and

(d) allowing separation and detection of an analyte in said sample in said gas chromatograph system to assess the presence, absence or amount of said analyte in said sample.

48. (previously presented): The gas chromatograph column of claim 1, wherein the compact material is selected from the group consisting of polymer, ceramic, silicon, quartz, glass and a combination thereof.

49. (previously presented): The gas chromatograph column of claim 1, wherein the lid layers and the channel layer comprise different compact materials.

50-51. (canceled)

52. (new): The gas chromatograph column of claim 1, wherein the lid and channel layers have a thickness ranging from about 0.1 to about 5 mm.

REMARKS

Status of the Claims

Claims 1-8 and 10-51 are currently pending in this application. Claims 29-47 have been withdrawn as being drawn to a nonelected invention. Claim 9 has been previously canceled. Claims 1-8, 10-28 and 48-51 have been examined and rejected.

In this amendment, claims 1 and 3 are amended to clarify the invention; claims 2, 26, 50 and 51 are canceled without prejudice or disclaimer; claims 27 and 28 are rewritten in independent form; and a new claim 52 is added. Support for the amendment may be found throughout the application as filed, for example, at page 5, lines 14-16 and page 6, lines 1-2, in Figure 3, and in claims 2 and 9. No new matter has been added. Upon entry of the amendment, claims 1, 3-8, 10-25, 27, 28, 48, 49 and 52 will be subject to further examination. Entry of the amendment and reconsideration on the merits in view of the following comments is respectfully requested.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Rejection under 35 U.S.C. § 102

Claims 1, 5, 8, 10-13, 15-24, and 48-49 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kaltenbach *et al.* (US 5,658,413, hereinafter "Kaltenbach").

Regarding claims 1, 5, and 8, the Office asserted that Kaltenbach discloses a miniaturized column device (abstract) comprising discrete first (64) and second (66) cover plates (Figs. 7A-B) and a discrete channel layer ("substrate 54", Figs. 7A-B) all having the same area (Figs. 7A-B), wherein said cover plates and channel layers comprise the same compact material (col. 4:3-10, col. 7:25-28, and col. 14:63-67), said channel layer comprises channels on both sides (Figs. 7A-B), said

channels and sides of said lid layers forming a first (60) and second (62) capillary (Figs. 7A-B), said capillaries are connected to each other through a hole to form an integrated capillary ("conduit means 72", Figs. 7A-B), said integrated capillary is connected to outside atmosphere on both ends via holes on two outermost cover plates ("apertures 78, 80", Figs. 7A-B), said cover plates and channel layer having a thickness ranging from about 0.1 to 5 mm (col. 18:25-34 and col. 19:39-43).

Applicants respectfully traverse this rejection for the following reasons.

The legal standard for anticipation under 35 U.S.C. § 102 is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. *In re Paulson*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (citing *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

As an initial matter, independent claim 1 has been amended to recite a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries. As noted above, support for this amendment is found at least at page 5, lines 14-16, in Figure 3, and in claim 2 of the application as filed. Since each of claims 5, 8, 10-13, 15-24, and 48-49 depends, directly or indirectly, from claim 1, all of these claims incorporate the new limitation as well.

As the Office has acknowledged in the OA, Kaltenbach does not teach or suggest a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer. Since Kaltenbach fails to teach each and every element of claims 1, 5, 8, 10-13, 15-24, and 48-49, it does not satisfy the strict identity standard for anticipation under 35 U.S.C. § 102(b). Accordingly, it is respectfully submitted that this rejection may properly be withdrawn.

Rejections under 35 U.S.C. § 103

Kaltenbach as a Single Reference

Claims 2-3, 26-28, 50 and 51 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kaltenbach as a single reference.

The Office has acknowledged that Kaltenbach does not expressly disclose a chromatography column comprising at least two lid layers and at least two channel layers. However, the Office asserted that it would have been obvious to one skilled in the art at the time of the invention to produce such a column comprising at least two lid layers and at least two channel layers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (MPEP § 2144.04.VI.B). The Office further stated that one could envisage from Kaltenbach that a chromatography column can comprise channel layers wherein one side of a channel layer directly faces another channel of an opposing channel layer to form a capillary.

As an initial matter, claims 2, 26, 50 and 51 have been canceled, thereby rendering moot all comments directed to these claims. With regard to claims 3, 27 and 28, Applicants respectfully traverse this rejection for the reasons set forth below.

The obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter must be considered. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) (*citing Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). In appropriate circumstances, a single prior art reference can render a claim obvious. However, there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion. This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000) (citations omitted; emphasis added).

As noted above, claim 1 has been amended to recite a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries. Since claim 3 depends from claim 1, this claim incorporates the new limitation as well. Additionally, as noted above, claim 26 has been canceled, and claims 27 and 28 have been rewritten in independent form.

The obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the differences between the claimed invention "as a whole" and the prior art. Thus, here it is critical to understand the difference between the claimed invention "as a whole" and Kaltenbach "as a whole".

The present invention is concerned with a portable (i.e., miniaturized) column for gas chromatography. More specifically, the present application states:

> Microfabrication technologies make it possible to build up a really potable gas chromatograph. The prior art, however, has not succeeded in the analysis of certain liquid samples with microfabricated gas chromatograph columns. The main reason is that **the microfabricated gas chromatograph columns are not long enough to attain satisfying separation effects**.
>
> (Page 1, line 26 – page 2, line 3; emphasis added).

Accordingly, the present application is aimed primarily at extending the length of the gas chromatography column in order to improve the quality of chromatographic separation.

In contrast, the cited invention of Kaltenbach, illustrated in Figs. 7A-B and described in detail at col. 18, line 25 – col. 20, line 7, is concerned primarily with extending the optical detection path length. The relevant passages are reproduced below for the sake of convenience:

> Further, as will be readily appreciated, **the use of optical detection means comprising apertures ablated into the substrate and cover plate provides great control over the effective detection pathlength in a miniaturized column device constructed herein**. In this regard, the detection pathlength will be substantially equal to the combined thickness of the substrate **4** and the cover plate **12**, and detection path lengths of up to 250 μm are readily obtainable using the subject detection means **42** in thin-film substrates such as polyimides.

Referring now to **FIG. 6**, it can be seen that apertures **34** and **36** provide an enlarged volume in separation compartment **14** at the point of intersection with the detection means **42**, where the enlarged volume will be proportional to the combined thickness of substrate 4 and cover plate **12**. In this manner, **sample plugs passing through separation compartment 14 can be subject to untoward distortion as the plug is influenced by the increased compartment volume in the detection area, especially where the combined thickness of the substrate and cover plate exceeds about 250 μm thereby possibly reducing separation efficiency in the device**.

Accordingly, in the present invention **wherein detection path lengths exceeding 250 μm are desired, an alternative device embodiment is provided having laser-ablated features on two opposing surfaces of a substrate**. More particularly, in **FIGS. 7A** and **7B**, a further embodiment of a miniaturized column device is generally indicated at **52**. The miniaturized column comprises a substrate **54** having first and second substantially planar opposing surfaces respectively indicated at **56** and **58**. The substrate **54** has a first microchannel **60** laser ablated in the first planar surface **56** and a second microchannel **62** laser ablated in the second planar surface **58**, wherein the microchannels can be provided in a wide variety of geometries, configurations and aspect ratios as described above…

Referring still to **FIGS. 7A** and **7B**, a plurality of apertures can be laser-ablated in the device to provide an extended separation compartment, and further to establish fluid communication means. More particularly, **a conduit means 72, comprising a laser ablated aperture in substrate 54 having an axis which is orthogonal to the first and second planar surfaces 56 and 58**, communicates a distal end **74** of the first microchannel **60** with a first end **76** of the second microchannel **62** to form an extended separation compartment.

(Kaltenbach at cols. 18:25-19:7, emphasis added.)

However, **a key feature of the laser-ablated conduit means 72 is the ability to provide an extended optical detection path length of up to 1 mm, or greater, without experiencing untoward sample plug distortion due to increased separation compartment volumes at the point of detection**. Referring to **FIGS. 7A**, **7B** and **9**, first and second transparent sheets, indicated at **82** and **84** respectively, can be provided such that the first cover plate **64** is interposed between the first transparent sheet and the first planar surface 56, and the second cover plate **66** is interposed between the second transparent sheet and the second planar surface **58**. The transparent sheets **82** and **84** can be

selected from appropriate materials such as quartz crystal, fused silica, diamond, sapphire and the like. Further, the transparent sheets can be provided having just enough surface area to cover and seal the apertures **78** and **80**, or those sheets can be sized to cover up to the entire surface area of the column device. As described above, this feature allows additional structural rigidity to be provided to a column device formed in a particularly thin substrate.

As best shown in FIG. 9, the subject arrangement allows optical detection of sample analytes passing through the miniaturized column device to be carried out along an optical detection path length 86 corresponding to the major axis of the conduit means 72. As will be readily appreciated, the optical detection path length 86 is substantially determined by the thickness of the substrate 54, and, accordingly, a great deal of flexibility in tailoring a miniaturized column device having μ-meter column dimensions and optical path lengths of up to 1 mm or greater is thereby enabled herein. In this manner, a wide variety of associated optical detection devices can be interfaced with the novel miniaturized columns, and detection of analytes in samples passing through the conduit means **72** can be readily carried out using UV/Vis, fluorescence, refractive index (RI), Raman and like spectrophotometric techniques.

(Kaltenbach at cols. 19:39-20:7, emphasis added.)

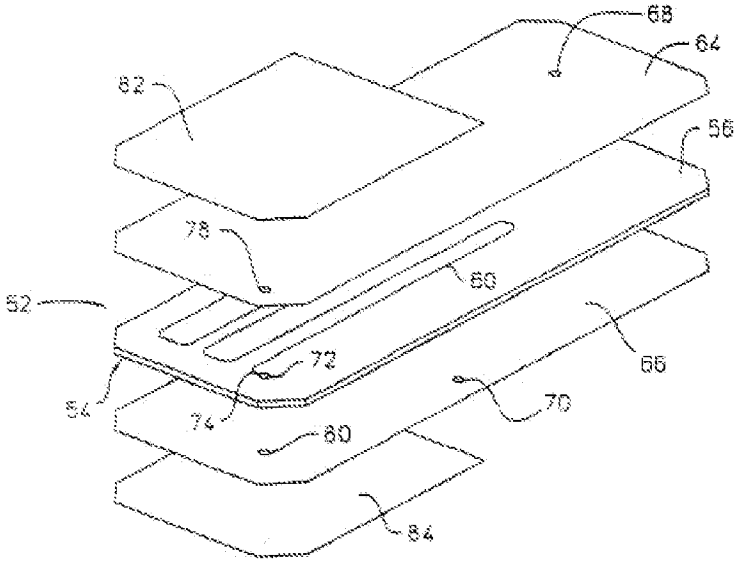


FIG. 7A

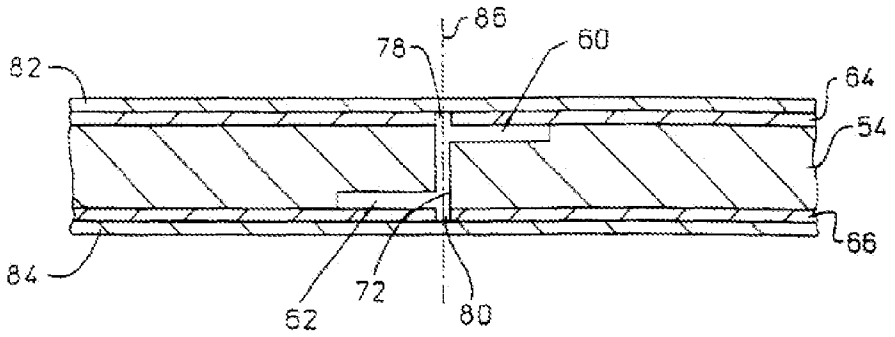


FIG. 9

Thus, the entire rationale behind the conduit means **72** (i.e., the hole through the channel layer) is to extend the optical detection path length **86**, and not to extend the length of the column. In fact, a careful reading of Kaltenbach reveals that there is not a single mention of a need to extend the length of the column. While Kaltenbach clearly identifies the problem of an insufficient optical detection path length, it does not appear to recognize the problem of an insufficient column length, which is the main target of the present invention.

The Office argues that it would have been obvious to a person skilled in the art at the time of the invention to produce a column comprising at least two lid layers and at least two channel layers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (MPEP § 2144.04.VI.B). The cited section of MPEP refers to *In re Harza* for the proposition that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). In essence, the Office uses a legal precedent as a source of a rationale to modify Kaltenbach. However, such use was recently questioned by the Board of Patent Appeals in *Ex parte Granneman*, 68 USPQ2d 1219 (B.P.A.I. 2003).

Much like here, at issue in *Ex parte Granneman* was the obviousness of the appellant's claimed semiconductor processing apparatus that differed from that disclosed in a Zinger prior art reference, in that claim 8 required a processing chamber containing two reactors whereas Zinger's

processing chambers each contain only one reactor. Thus, "to arrive at the appellant's claimed apparatus, Zinger's apparatus must be modified by including a second reactor in the reactor compartment." The examiner argued, in reliance upon *In re Harza*, that an additional reactor in Zinger's processing chamber would be a mere duplication of parts and, therefore, would have been obvious to one of ordinary skill in the art.

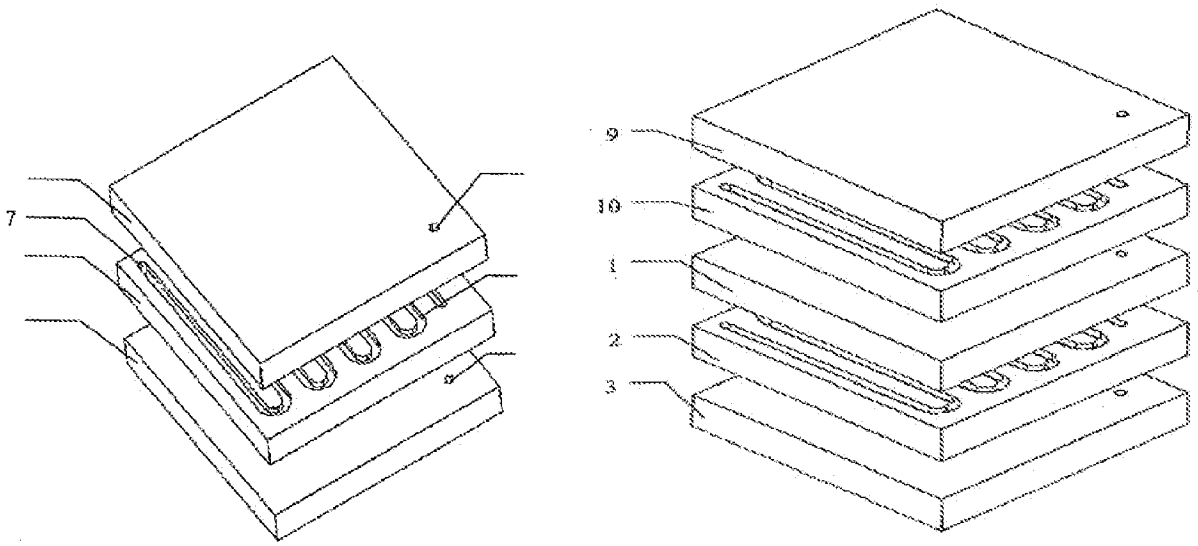
The Board noted that the court in *In re Harza* had stated that the only difference between the reference's structure for sealing concrete and that of *Harza*'s claim 1 was that the reference structure had only a single rib (i.e., arm) on each side of a web, whereas the claim required a plurality of such ribs, and that the court in *In re Harza* had held "[i]t is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced, and we are of the opinion that such is not the case here." The Board further stated:

> The Examiner does not compare the facts in *Harza* with those in the present case and explain why, based on his comparison, the legal conclusion in the present case should be the same as that in *Harza*. Instead, the examiner relies upon *Harza* as establishing a *per se* rule that duplication of parts is obvious. As stated by the Federal Circuit in *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995), "reliance on *per se* rules of obviousness is legally incorrect and must cease."
>
> *Ex parte Granneman*, 68 USPQ2d 1219, 1220 (B.P.A.I. 2003)

The Board eventually reversed the examiner on the ground that he had not explained why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification, and therefore he had not established a *prima facie* case of obviousness of the appellant's claimed invention. Even though *Ex parte Granneman* is a pre-*KSR* case, the principle that a legal precedent cannot be used as a sole rationale to modify a prior art reference is still valid.

Moreover, modifying the device of Kaltenbach shown in Figs. 7A-B in the manner disclosed in the present application would defeat the main purpose of Kaltenbach's invention. As noted above, Kaltenbach teaches that the main purpose of the conduit means **72** is to extend the optical detection path length **86** of the chromatography column. Accordingly, it is important that both

apertures **78** and **80** remain unobstructed in order for the optical detection to work. Stacking the devices shown in Figs. 7A-B of Kaltenbach on top of one another in the manner consistent with the present invention (*see, e.g.*, Figs. 1A and 3, reproduced below) would result in obstruction of the optical path because the apertures in the lid layers are misaligned with the apertures (**7**) in the channel layers.



Thus, it is apparent that modifying Kaltenbach in the manner consistent with the present application would produce a result that is contrary to the one Kaltenbach is trying to achieve. It is well settled law, however, that if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01, *citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court

reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

Based on the foregoing, a person skilled in the art at the time of the invention could not have been motivated to modify the teachings of Kaltenbach to arrive at the presently claimed invention with a reasonable expectation of success. Since there was no adequate motivation to modify the teachings of Kaltenbach in the manner consistent with the present application with a reasonable expectation of success, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) may properly be withdrawn.

Kaltenbach in View of Craig

Claims 4 and 14 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kaltenbach in view of Craig (US 5,792,943, hereinafter "Craig").

The Office has acknowledged that Kaltenbach fails to teach a chromatography column comprising a compact material wherein said compact material is metal, and the length of said column is at least 4 meters. To cure this deficiency of Kaltenbach, the Office cited Craig, which allegedly teaches a gas chromatography column comprising a compact material wherein said compact material is metal, and the length of said column is at least 4 meters.

The Office asserted that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Craig with the chromatography column of Kaltenbach because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Applicants respectfully traverse this rejection.

As noted above, claim 1 has been amended to recite a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries. Since claims 4 and 14 directly depend from claim 1, both of these claims incorporate the new limitation as well.

The relevant teachings and deficiencies of Kaltenbach are discussed above. Briefly, Kaltenbach does not teach or suggest a gas chromatograph column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries.

Craig discloses a planar separation column device that includes complementary microstructures formed in a planar foldable substrate (abstract, Figs. 3-13). Craig specifically teaches that "[i]t is a primary feature of the present invention to construct the integrated assembly from a planar substrate having at least first and second component sections separated by a linear fold means, wherein said substrate is comprised of a material that is ductile in the region of the linear fold means and substantially inextensible in the regions defined by the component sections" (col. 4, lines 3-9, emphasis added). Craig explains that "[t]he fold means constrains the co-location of the microstructures with extreme accuracy due to the inextensibility of the substrate with respect to the fold axis" which facilitates joining "the complementary microstructures… with precise alignment" (col. 4, lines 33-37, emphasis added).

In fact, a comparison of Craig and Kaltenbach reveals that both references disclose essentially the same chromatography column configuration (*cf., e.g.*, Figs. 8A-B of Kaltenbach and Figs. 6A-B of Craig). Much like Kaltenbach, Craig does not teach or suggest a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries.

Since the combination of Kaltenbach and Craig fails to teach each and every limitation of the claims 4 and 14 as amended, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) may properly be withdrawn.

Kaltenbach in View of Goedert

Claims 6-7, 25 and 50 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kaltenbach in view of Goedert (US 4,935,040, hereinafter "Goedert"). Since the OA contains no discussion of how Goedert applies to the additional limitation of claim 50, Applicants will presume that this rejection was raised against claim 50 unintentionally.

The Office has acknowledged that Kaltenbach fails to teach a chromatography column wherein the area of lid and channel layers forming said column is from about 1 to 100 cm^2 and further comprises a heater wire on an outside surface of the integrated capillary. To cure this deficiency of Kaltenbach, the Office cited Goedert, which allegedly teaches a gas chromatography column wherein the lid layers and channel layers have an area ranging from about 1 to about 100 cm^2, and having a heater wire deposited on an outside surface of the integrated capillary to provide for electric heating of a stationary phase material within the integrated capillary during operation of a gas chromatograph in order to provide a heating apparatus that is electrically controlled for selective heating of a stationary phase material within the integrated capillary.

The Office asserted that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Goedert with the chromatography column of Kaltenbach because all the claimed elements were known in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Applicants respectfully traverse this rejection.

As noted above, claim 1 has been amended to recite a gas chromatography column comprising more than two discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries. Since each of claims 6-7 and 25 depends from claim 1, all these claims incorporate the new limitation as well.

The relevant teachings and deficiencies of Kaltenbach are discussed above. Briefly, Kaltenbach does not teach or suggest a gas chromatograph column comprising more than two

discrete lid layers and more than one discrete channel layer, wherein said microfabricated channels and sides of said lid layers form at least four capillaries.

Goedert discloses a unitary gas chromatographic device comprising a body formed of a multiplicity of wafer members laminated together, wherein the wafer members have mating surfaces with channels formed therein such as to define a plurality of gas chromatographic columns in the body. *See* Goedert at col. 2:22-26. However, Goedert does not teach or suggest channel layers having microchannels on both sides. Instead, Goedert discloses a gas chromatography device wherein wafer pairs are first laminated together to form capillaries (Fig. 2, col. 4, lines 23-24). After that, a plurality of wafer pairs are stacked and laminated together to form a unitary body and to align a corresponding plurality of chromatographic capillaries (Fig. 1, col. 4, lines 61-65). The capillaries formed within each wafer pair may be linked by connecting microchannels aligned pairwise to lead perpendicularly through the laminated wafer pairs (Fig. 1, col. 5, lines 3-6). Thus, in Goedert, the microchannels are formed within each wafer pair (i.e., the microchannel is always on one side of a wafer), which is different from the chromatography column of the present claim 1, wherein the channel layers have microchannels on both sides that can form capillaries with the lid layers and/or other channel layers.

A person skilled in the art at the time of the invention would not have been motivated to combine the teachings of Kaltenbach with those of Goedert for a number of reasons. First, Goedert teaches a device for gas chromatography, whereas Kaltenbach teaches a device for liquid chromatography, which has distinct structural requirements. Second, the inventions of Kaltenbach and Goedert aim to solve completely different problems. As discussed above, the invention of Kaltenbach is aimed primarily at extending the detection path for optical detection of liquid analytes, which is achieved by making a hole in the channel layer and placing microchannels on both sides. As a result, the optical detection path is not limited by the width/depth of the capillary and instead depends on the thickness of the channel layer. In contrast, the invention of Goedert is aimed at extending the overall length of the capillary, which is accomplished by stacking and aligning laminated wafer pairs. Since the inventions solve very different problems, it is not readily apparent why a person skilled in the art at the time of the invention would be motivated to combine

the stacked arrangement of Goedert with the double-sided channel layer taught in Kaltenbach. Indeed, if one were to stack the double-sided channel layer of Kaltenbach in the manner taught in Goedert, one could not reasonably expect to accomplish the principal goal of Kaltenbach, i.e., to extend the optical detection path, for the reasons discussed in detail above.

Since the combination of Kaltenbach and Goedert fails to teach each and every limitation of the claims 6-7 and 25 as amended, and there was no adequate motivation to combine the references with a reasonable expectation of success, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) may properly be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. 514572000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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